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PATENT

Docket No.: 20747/270 (ARDBW/P29257US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Axel Thomson

Serial No. : 10/528,267

Cnfrm. No. : To Be Assigned

Filed : September 17, 2003

For : A METHOD OF PROTECTING A PATIENT
FROM POSSIBLE ADVERSE EFFECTS OF
INHIBITION OF THE SHH-SIGNALING
PATHWAY BY SUPPRESSING
TESTOSTERONE OR ITS EFFECTS IN THE
PATIENT

Examiner:
To Be Assigned J. Ha

Art Unit:
To Be Assigned 1654

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97-1.98

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Pursuant to 37 CFR §§ 1.97-1.98, applicant hereby brings to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO/SB/08 form.

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. Patents (i.e., Reference Cite Nos. 1-2) are not enclosed. Copies of all other listed references (i.e., Reference Cite Nos. 3-67) are enclosed herewith.

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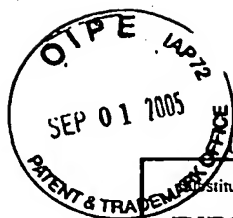
Respectfully submitted,

Date: August 29, 2005

Edwin V. Merkel
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
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Sheet	1	of	6	Attorney Docket Number	20747/270 (ARDBW/P29257US)

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/JH/	1	US-4,946,779	08-07-1990	Kameda et al.	
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/JH/	3	WO 99/52534 A1	10-21-1999	Beachy et al.		
	4	WO 00/41545 A1	07-20-2000	Dudek		
	5	WO 01/27135 A2	04-19-2001	Beachy		
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	12	BITGOOD & McMAHON, "Hedgehog and <i>Bmp</i> Genes Are Coexpressed at Many Diverse Sites of Cell-Cell Interaction in the Mouse Embryo," <i>Dev. Biol.</i> 172:126-138 (1995)	
	13	BOSTWICK et al., "Prostatic Intra-Epithelial Neoplasia and Early Invasion in Prostate Cancer," <i>Cancer</i> 59:788-794 (1987)	
	14	CHEN et al., "Inhibition of Hedgehog Signaling by Direct Binding of Cyclopamine to Smoothened," <i>Genes Dev.</i> 16:2743-2748 (2002)	
	15	CHEN et al., "Small Molecule Modulation of Smoothened Activity," <i>Proc. Natl. Acad. Sci. USA</i> 99(22):14071-14076 (2002)	
	16	CHIANG et al., "Cyclopia and Defective Axial Patterning in Mice Lacking <i>Sonic Hedgehog</i> Gene Function," <i>Nature</i> 383:407-413 (1996)	
	17	CHIANG et al., "Essential Role for <i>Sonic hedgehog</i> During Hair Follicle Morphogenesis," <i>Dev. Biol.</i> 205:1-9 (1999)	
	18	CHOMCZYNSKI et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction," <i>Anal. Biochem.</i> 162:156-159 (1987)	
	19	COLE et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer," <i>Monoclonal Antibodies and Cancer Therapy</i> , Alan R. Liss, Inc., pp.77-96 (1985)	
	20	COTE et al., "Generation of Human Monoclonal Antibodies Reactive with Cellular Antigens," <i>Proc. Natl. Acad. Sci. USA</i> 80:2026-2030 (1983)	
	21	CUNHA & CHUNG, "Stromal-Epithelial Interactions-I. Induction of Prostatic Phenotype in Urothelium of Testicular Feminized (Tfm/y) Mice," <i>J. Steroid Biochem.</i> 14:1317-1321 (1981)	
↓	22	CUNHA et al., "Smooth Muscle-Epithelial Interactions in Normal and Neoplastic Prostatic Development," <i>Acta Anat.</i> 155:63-72 (1996)	

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/JH/	23	EPSTEIN, J.I., "Nonspecific Granulomatous Prostatitis vs. Infectious Granulomas," in <i>Differential Diagnosis in Pathology: Urologic Disorders</i> , Section 3: Prostate, New York, Igaku-Shoin Ltd., pp.74-136 (1992)	
	24	FREEMAN et al., "A Comparison of Basal Cell Markers Used in the Prostate," <i>Histopathology</i> 40:483-494 (2002)	
	25	FROHMAN et al., "Isolation of the Mouse <i>Hox-2.9</i> Gene; Analysis of Embryonic Expression Suggests that Positional Information Along the Anterior-Posterior Axis is Specified by Mesoderm," <i>Development</i> 110:589-607 (1990)	
	26	GAO et al., "Conversion from a Paracrine to an Autocrine Mechanism of Androgen-Stimulated Growth during Malignant Transformation of Prostatic Epithelial Cells," <i>Cancer Res.</i> 61:5038-5044 (2001)	
	27	GENBANK ACCESSION NO. U43148 (1996)	
	28	GENBANK ACCESSION NO. L38518 (1995)	
	29	GENBANK ACCESSION NO. U84401 (1997)	
	30	GENBANK ACCESSION NO. AF316573 (2002)	
	31	GENBANK ACCESSION NO. AB007298 (2002)	
	32	GENBANK ACCESSION NO. M57609 (1994)	
	33	HARAGUCHI et al., "Unique Functions of Sonic Hedgehog Signaling During External Genitalia Development," <i>Development</i> 128:4241-4250 (2001)	
	34	HAYWARD et al., "Epithelial Development in the Rat Ventral Prostate, Anterior Prostate and Seminal Vesicle," <i>Acta Anat.</i> 155:81-93 (1996)	

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/JH/	35	HAYWARD et al., "Interactions Between Adult Human Prostatic Epithelium and Rat Urogenital Sinus Mesenchyme in a Tissue Recombination Model," <i>Differentiation</i> 63:131-140 (1998)	
	36	INCARDONA et al., "The Teratogenic <i>Veratrum</i> Alkaloid Cyclopamine Inhibits Sonic Hedgehog Signal Transduction," <i>Development</i> 125:3553-3562 (1998)	
	37	KIM et al., "Nkx3.1 Mutant Mice Recapitulate Early Stages of Prostate Carcinogenesis," <i>Cancer Res.</i> 62:2999-3004 (2002)	
	38	KIM et al., "Pancreas Development is Promoted by Cyclopamine, a Hedgehog Signaling Inhibitor," <i>Proc. Natl. Acad. Sci. USA</i> 95:13036-13041 (1998)	
	39	KÖHLER & MILSTEIN, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity," <i>Nature</i> 256:495-497 (1975)	
	40	KOZBOR & RODER, "The Production of Monoclonal Antibodies from Human Lymphocytes," <i>Immunol. Today</i> 4(3):72-79 (1983)	
	41	LAMM et al., "Mesenchymal Factor Bone Morphogenetic Protein 4 Restricts Ductal Budding and Branching Morphogenesis in the Developing Prostate," <i>Dev. Biol.</i> 232:301-314 (2001)	
	42	LAMM et al., "Sonic Hedgehog Activates Mesenchymal <i>Gli1</i> Expression during Prostate Ductal Bud Formation," <i>Dev. Biol.</i> 249:349-366 (2002)	
	43	MORRISON et al., "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains," <i>Proc. Natl. Acad. Sci. USA</i> 81:6851-6855 (1984)	
	44	NEUBERGER et al., "Recombinant Antibodies Possessing Novel Effector Functions," <i>Nature</i> 312:604-608 (1984)	
	45	NOGAWA et al., "Bud Formation Precedes the Appearance of Differential Cell Proliferation During Branching Morphogenesis of Mouse Lung Epithelium In Vitro," <i>Dev. Dyn.</i> 213:228-235 (1998)	
	46	OLUMI et al., "Carcinoma-Associated Fibroblasts Direct Tumor Progression of Initiated Human Prostatic Epithelium," <i>Cancer Res.</i> 59:5002-5011 (1999)	

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/JH/	47	ORLANDI et al., "Cloning Immunoglobulin Variable Domains for Expression by the Polymerase Chain Reaction," <i>Proc. Natl. Acad. Sci. USA</i> 86:3833-3837 (1989)	
	48	PARSONS et al., "p63 Protein Expression is Rare I Prostate Adenocarcinoma: Implications for Cancer Diagnosis and Carcinogenesis," <i>Urology</i> 58:619-624 (2001)	
	49	PATHI et al., "Comparative Biological Responses to Human Sonic, Indian, and Desert Hedgehog," <i>Mech. Dev.</i> 106:107-117 (2001)	
	50	PEPICELLI et al., "Sonic Hedgehog Regulates Branching Morphogenesis in the Mammalian Lung," <i>Curr. Biol.</i> 8:1083-1086 (1998)	
	51	PERRITON et al., "Sonic hedgehog Signaling from the Urethral Epithelium Controls External Genital Development," <i>Dev. Biol.</i> 247:26-46 (2002)	
	52	RAMALHO-SANTOS et al., "Hedgehog Signals Regulate Multiple Aspects of Gastrointestinal Development," <i>Development</i> 127:2763-2772 (2000)	
	53	ROELINK et al., "Floor Plate and Motor Neuron Induction by <i>vhh-1</i> , a Vertebrate Homolog of <i>hedgehog</i> Expressed by the Notochord," <i>Cell</i> 76:761-775 (1994)	
	54	RUIZ I ALTABA et al., "Gli and Hedgehog in Cancer: Tumours, Embryos and Stem Cells," <i>Nat. Rev. Cancer</i> 2:361-372 (2002)	
	55	SCHNEIDER et al., "Targeted Disruption of the Nkx3.1 Gene in Mice Results in Morphogenetic Defects of Minor Salivary Glands: Parallels to Glandular Duct Morphogenesis in Prostate," <i>Mech. Dev.</i> 95:163-174 (2000)	
	56	STONE et al., "The Tumour-Suppressor Gene <i>Patched</i> Encodes a Candidate Receptor for Sonic Hedgehog," <i>Nature</i> 384:129-134 (1996)	
	57	SUGIMURA et al., "Keratinocyte Growth Factor (KGF) Can Replace Testosterone in the Ductal Branching Morphogenesis of the Rat Ventral Prostate," <i>Int. J. Dev. Biol.</i> 40:941-951 (1996)	
✓	58	SUGIMURA et al., "Morphogenesis of Ductal Networks in the Mouse Prostate," <i>Biol. Reprod.</i> 34:961-971 (1986)	

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	60	TAKEDA et al., "Construction of Chimaeric Processed Immunoglobulin Genes Containing Mouse Variable and Human Constant Region Sequences," <i>Nature</i> 314:452-454 (1985)	
	61	THOMSON & CUNHA, "Prostatic Growth and Development are Regulated by FGF10," <i>Development</i> 126:3693-3701 (1999)	
	62	THOMSON et al., "Analysis of Growth Factor and Receptor mRNA Levels During Development of the Rat Seminal Vesicle and Prostate," <i>Development</i> 124:2431-2439 (1997)	
	63	THOMSON et al., "The Role of Smooth Muscle in Regulating Prostatic Induction," <i>Development</i> 129:1905-1912 (2002)	
	64	TOTTEN et al., "Microscopic Differential Diagnosis of Latent Carcinoma of Prostate," <i>Arch. Pathol.</i> 55:131-141 (1953)	
	65	WANG et al., "Cell Differentiation Lineage in the Prostate," <i>Differentiation</i> 68:270-279 (2001)	
	66	WINTER & MILSTEIN, "Man-made Antibodies," <i>Nature</i> 349:293-299 (1991)	
	67	WOJNO et al., "The Utility of Basal Cell-Specific Anti-Cytokeratin Antibody (34 β E12) in the Diagnosis of Prostate Cancer," <i>Am. J. Surg. Pathol.</i> 19(3):251-260 (1995)	

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	11	BHATIA-GAUR et al., "Roles for <i>Nkx3.1</i> in Prostate Development and Cancer," <i>Genes Dev.</i> 13:966-977 (1999)	
	12	BITGOOD & McMAHON, "Hedgehog and <i>Bmp</i> Genes Are Coexpressed at Many Diverse Sites of Cell-Cell Interaction in the Mouse Embryo," <i>Dev. Biol.</i> 172:126-138 (1995)	
	13	BOSTWICK et al., "Prostatic Intra-Epithelial Neoplasia and Early Invasion in Prostate Cancer," <i>Cancer</i> 59:788-794 (1987)	
	14	CHEN et al., "Inhibition of Hedgehog Signaling by Direct Binding of Cyclopamine to Smoothened," <i>Genes Dev.</i> 16:2743-2748 (2002)	
	15	CHEN et al., "Small Molecule Modulation of Smoothened Activity," <i>Proc. Natl. Acad. Sci. USA</i> 99(22):14071-14076 (2002)	
	16	CHIANG et al., "Cyclopia and Defective Axial Patterning in Mice Lacking <i>Sonic Hedgehog</i> Gene Function," <i>Nature</i> 383:407-413 (1996)	
	17	CHIANG et al., "Essential Role for <i>Sonic hedgehog</i> During Hair Follicle Morphogenesis," <i>Dev. Biol.</i> 205:149 (1999)	
	18	CHOMCZYNSKI et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction," <i>Anal. Biochem.</i> 162:156-159 (1987)	
	19	COLE et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer," <i>Monoclonal Antibodies and Cancer Therapy</i> , Alan R. Liss, Inc., pp.77-96 (1985)	
	20	COTE et al., "Generation of Human Monoclonal Antibodies Reactive with Cellular Antigens," <i>Proc. Natl. Acad. Sci. USA</i> 80:2026-2030 (1983)	
	21	CUNHA & CHUNG, "Stromal-Epithelial Interactions-I. Induction of Prostatic Phenotype in Urothelium of Testicular Feminized (Tfm/y) Mice," <i>J. Steroid Biochem.</i> 14:1317-1321 (1981)	
	22	CUNHA et al., "Smooth Muscle-Epithelial Interactions in Normal and Neoplastic Prostatic Development," <i>Acta Anat.</i> 155:63-72 (1996)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/528,267
				Filing Date	September 17, 2003
				First Named Inventor	Axel Thomson
				Group Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
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	23	EPSTEIN, J.I., "Nonspecific Granulomatous Prostatitis vs. Infectious Granulomas," in <i>Differential Diagnosis in Pathology: Urologic Disorders</i> , Section 3: Prostate, New York, Igaku-Shoin Ltd., pp. 74-136 (1992)	
	24	FREEMAN et al., "A Comparison of Basal Cell Markers Used in the Prostate," <i>Histopathology</i> 40:483-494 (2002)	
	25	FRONMAN et al., "Isolation of the Mouse <i>Hox-2.9</i> Gene; Analysis of Embryonic Expression Suggests that Positional Information Along the Anterior-Posterior Axis is Specified by Mesoderm," <i>Development</i> 110:589-607 (1990)	
	26	GAO et al., "Conversion from a Paracrine to an Autocrine Mechanism of Androgen-Stimulated Growth During Malignant Transformation of Prostatic Epithelial Cells," <i>Cancer Res.</i> 61:5038-5044 (2001)	
	27	GENBANK ACCESSION NO. U43148 (1996)	
	28	GENBANK ACCESSION NO. L38518 (1995)	
	29	GENBANK ACCESSION NO. U84401 (1997)	
	30	GENBANK ACCESSION NO. AF316573 (2002)	
	31	GENBANK ACCESSION NO. AB007298 (2002)	
	32	GENBANK ACCESSION NO. M57609 (1994)	
	33	HARAGUCHI et al., "Unique Functions of Sonic Hedgehog Signaling During External Genitalia Development," <i>Development</i> 128:4241-4250 (2001)	
	34	HAYWARD et al., "Epithelial Development in the Rat Ventral Prostate, Anterior Prostate and Seminal Vesicle," <i>Acta Anat.</i> 155:81-93 (1996)	

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	35	HAYWARD et al., "Interactions Between Adult Human Prostatic Epithelium and Rat Urogenital Sinus Mesenchyme in a Tissue Recombination Model," <i>Differentiation</i> 63:131-140 (1998)	
	36	INCARDONA et al., "The Teratogenic <i>Veratrum</i> Alkaloid Cyclopamine Inhibits Sonic Hedgehog Signal Transduction," <i>Development</i> 125:3553-3562 (1998)	
	37	KIM et al., "Nkx3.1 Mutant Mice Recapitulate Early Stages of Prostate Carcinogenesis," <i>Cancer Res.</i> 62:2999-3004 (2002)	
	38	KIM et al., "Pancreas Development is Promoted by Cyclopamine, a Hedgehog Signaling Inhibitor," <i>Proc. Natl. Acad. Sci. USA</i> 95:13036-13041 (1998)	
	39	KÖHLER & MILSTEIN, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity," <i>Nature</i> 256:495-497 (1975)	
	40	KOZBOR & RÖDER, "The Production of Monoclonal Antibodies from Human Lymphocytes," <i>Immunol. Today</i> 4(3):72-79 (1983)	
	41	LAMM et al., "Mesenchymal Factor Bone Morphogenetic Protein 4 Restricts Ductal Budding and Branching Morphogenesis in the Developing Prostate," <i>Dev. Biol.</i> 232:301-314 (2001)	
	42	LAMM et al., "Sonic Hedgehog Activates Mesenchymal <i>Gli1</i> Expression during Prostate Ductal Bud Formation," <i>Dev. Biol.</i> 249:349-366 (2002)	
	43	MORRISON et al., "Chimeric Human Antibody Molecules: Mouse Antigen-Binding Domains with Human Constant Region Domains," <i>Proc. Natl. Acad. Sci. USA</i> 81:6851-6855 (1984)	
	44	NEUBERGER et al., "Recombinant Antibodies Possessing Novel Effector Functions," <i>Nature</i> 312:604-608 (1984)	
	45	NOGAWA et al., "Bud Formation Precedes the Appearance of Differential Cell Proliferation During Branching Morphogenesis of Mouse Lung Epithelium In Vitro," <i>Dev. Dyn.</i> 213:228-235 (1998)	
	46	OLUMI et al., "Carcinoma-Associated Fibroblasts Direct Tumor Progression of Initiated Human Prostatic Epithelium," <i>Cancer Res.</i> 59:5002-5011 (1999)	

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Sheet	5	of	6	Attorney Docket Number	20747/270 (ARDBW/P29257US)

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	47	ORLANDI et al., "Cloning Immunoglobulin Variable Domains for Expression by the Polymerase Chain Reaction," <i>Proc. Natl. Acad. Sci. USA</i> 86:3833-3837 (1989)	
	48	PARSONS et al., "p63 Protein Expression is Rare I Prostate Adenocarcinoma: Implications for Cancer Diagnosis and Carcinogenesis," <i>Urology</i> 58:619-624 (2001)	
	49	PATHI et al., "Comparative Biological Responses to Human Sonic, Indian, and Desert Hedgehog," <i>Mech. Dev.</i> 106:107-117 (2001)	
	50	PEPICELLI et al., "Sonic Hedgehog Regulates Branching Morphogenesis in the Mammalian Lung," <i>Curr. Biol.</i> 8:1083-1086 (1998)	
	51	PERRITON et al., "Sonic hedgehog Signaling from the Urethral Epithelium Controls External Genital Development," <i>Dev. Biol.</i> 247:26-46 (2002)	
	52	RAMALHO-SANTOS et al., "Hedgehog Signals Regulate Multiple Aspects of Gastrointestinal Development," <i>Development</i> 127:2763-2772 (2000)	
	53	ROELINK et al., "Floor Plate and Motor Neuron Induction by <i>vhh-1</i> , a Vertebrate Homolog of <i>hedgehog</i> Expressed by the Notochord," <i>Cell</i> 76:761-775 (1994)	
	54	RUIZ I ALTABA et al., "Gli and Hedgehog in Cancer: Tumours, Embryos and Stem Cells," <i>Nat. Rev. Cancer</i> 2:361-372 (2002)	
	55	SCHNEIDER et al., "Targeted Disruption of the <i>Nkx3.1</i> Gene in Mice Results in Morphogenetic Defects of Minor Salivary Glands: Parallels to Glandular Duct Morphogenesis in Prostate," <i>Mech. Dev.</i> 95:163-174 (2000)	
	56	STONE et al., "The Tumour-Suppressor Gene <i>Patched</i> Encodes a Candidate Receptor for Sonic Hedgehog," <i>Nature</i> 384:129-134 (1996)	
	57	SUGIMURA et al., "Keratinocyte Growth Factor (KGF) Can Replace Testosterone in the Ductal Branching Morphogenesis of the Rat Ventral Prostate," <i>Int. J. Dev. Biol.</i> 40:941-951 (1996)	
	58	SUGIMURA et al., "Morphogenesis of Ductal Networks in the Mouse Prostate," <i>Biol. Reprod.</i> 34:961-971 (1986)	

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				Filing Date	September 17, 2003
				First Named Inventor	Axel Thomson
				Group Art Unit	To Be Assigned
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Sheet	6	of	6	Attorney Docket Number	20747/270 (ARDBW/P29257US)

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	59	SUKEGAWA et al., "The Concentric Structure of the Developing Gut is Regulated by Sonic Hedgehog Derived from Endodermal Epithelium," <i>Development</i> 127:1971-1980 (2000)	
	60	TAKEDA et al., "Construction of Chimaeric Processed Immunoglobulin Genes Containing Mouse Variable and Human Constant Region Sequences," <i>Nature</i> 314:452-454 (1985)	
	61	THOMSON & CUNHA, "Prostatic Growth and Development are Regulated by FGF10," <i>Development</i> 126:3693-3701 (1999)	
	62	THOMSON et al., "Analysis of Growth Factor and Receptor mRNA Levels During Development of the Rat Seminal Vesicle and Prostate," <i>Development</i> 124:2431-2439 (1997)	
	63	THOMSON et al., "The Role of Smooth Muscle in Regulating Prostatic Induction," <i>Development</i> 129:1905-1912 (2002)	
	64	TOTTEN et al., "Microscopic Differential Diagnosis of Latent Carcinoma of Prostate," <i>Arch. Pathol.</i> 55:131-141 (1953)	
	65	WANG et al., "Cell Differentiation Lineage in the Prostate," <i>Differentiation</i> 68:270-279 (2001)	
	66	WINTER & MILSTEIN, "Man-made Antibodies," <i>Nature</i> 349:293-299 (1991)	
	67	WOJNO et al., "The Utility of Basal Cell-Specific Anti-Cytokeratin Antibody (34BE12) in the Diagnosis of Prostate Cancer," <i>Am. J. Surg. Pathol.</i> 19(3):251-260 (1995)	

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PATENT
Docket No.: 20747/270 (ARDBW/P29257US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Axel Andreas THOMSON)
U. S. Serial No:	To be assigned)
Filed:	Herewith)
PCT International Application No:	PCT/GB2003/004117)
Filed:	17 September 2003)
For :	A METHOD OF PROTECTING A PATIENT FROM POSSIBLE ADVERSE EFFECTS OF INHIBITION OF THE SHH-SIGNALLING PATHWAY BY SUPPRESSING TESTOSTERONE OR ITS EFFECTS IN THE PATIENT)

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In compliance with 37 C.F.R. 1.56, 1.97, and 1.98, published art included in the International Search Report (copy enclosed) of the corresponding PCT application, is cited for consideration and listed on the enclosed PTO-1449 form as references 1-3. These references are relevant for the reasons given in the search report.

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applicants (i.e., the ISA has not provided them), the PTO should contact the undersigned representative directly.

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Respectfully submitted,

Date: March 17, 2005



Edwin V. Merkel
Registration No. 40,087

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1128
Facsimile: (585) 263-1600

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				Filing Date	Herewith
				First Named Inventor	Axel Andreas Thomson
				Art Unit	To Be Assigned 1694
				Examiner Name	To Be Assigned J. Ha
Sheet 1		of 1		Attorney Docket Number	20747/270 (ARDBW/P29257US)

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/JH/	1	Berman et al., "Medulloblastoma growth inhibition by Hedgehog pathway blockade", <u>Science</u> , 297(5586):1559-1561 (2002).	
/JH/	2	Podlasek et al., "Prostate development requires Sonic hedgehog expressed by the urogenital sinus epithelium", <u>Developmental Biology</u> , 209 (1):28-39 (1999).	
/JH/	3.	Bergman et al., "Inhibition of prostate morphogenesis by the sonic hedgehog pathway inhibitor cyclopamine", <u>Journal of Urology</u> , 163(4 suppl.):204 (2000).	

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